ORAL ARGUMENT NOT YET SCHEDULED
No. 24-1135 (consolidated with Nos. 24-1228; 24-1246; 24-1249; 24-1250, 24-1251, 24-1252)

UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

DENKA PERFORMANCE ELASTOMER, LLC, *et al.*,
Petitioners,
v.
ENVIRONMENTAL PROTECTION AGENCY, *et al.*,
Respondents,

and

AIR ALLIANCE HOUSTON, *et al.*,
Intervenors for Respondent.

On Petition for Review of a Final Agency Action
of the Environmental Protection Agency

AMICUS CURIAE BRIEF OF THE ETHYLENE OXIDE STERILIZATION ASSOCIATION IN SUPPORT OF PETITIONERS AND VACATUR

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CERTIFICATE AS TO PARTIES, RULINGS, AND RELATED CASES

Pursuant to Circuit Rule 28(a)(1), amicus curiae The Ethylene Oxide Sterilization Association, Inc. states as follows:

A. Parties and Amici:

Except for the following, all parties, intervenors, and amicus curiae appearing in these consolidated cases are listed in the Brief of Petitioners American Chemistry Council, et al.

Amicus Curiae brief of The Ethylene Oxide Sterilization Association, Inc.

B. Rulings under Review:

Reference to the orders under review appear on pages i-ii of the Brief of Petitioners American Chemistry Council, et al.

C. Related Cases

Reference to related cases to this appeal appear on page ii of the Brief of Petitioners American Chemistry Council, et al.

CORPORATE DISCLOSURE STATEMENT

Pursuant to Federal Rule of Appellate Procedure 26.1 and D.C. Circuit Rule 26.1, The Ethylene Oxide Sterilization Association, Inc. ("EOSA") states the following:

EOSA is a nonprofit organization incorporated in the District of Columbia for the purpose of representing members of the ethylene oxide sterilizing industry to promote and enhance the safe use of ethylene oxide for sterilization purposes. EOSA has no parent company, subsidiary, or affiliates. No publicly held company has a 10% or greater ownership interest in EOSA.

CIRCUIT RULE 29(D) CERTIFICATE

Amicus Curiae The Ethylene Oxide Sterilization Association, Inc. ("EOSA") certifies that a separate amicus brief is necessary. Amicus Curiae is not aware of other entities or individuals intending to participate as amici to represent the perspectives and interests of the ethylene oxide sterilization industry.

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GLOSSARY

CAA	Clean Air Act
EOSA	The Ethylene Oxide Sterilization Association
EPA	The U.S. Environmental Protection Agency
EtO	Ethylene Oxide
HAP	Hazardous Air Pollutant

INTEREST OF AMICUS CURIAE AND INTRODUCTION[1]

The Ethylene Oxide Sterilization Association ("EOSA"), a non-profit comprised of members of the ethylene oxide ("EtO") sterilizing industry, submits this amicus brief in support of Petitioners.

Like Petitioners, EOSA's members, which include medical device sterilization facilities, are a target of EPA's recent claim of authority to increase the stringency of hazardous air pollutant ("HAP") standards under Clean Air Act ("CAA") Section 112(f)(2) with no regard to cost. And like Petitioners, EOSA's sterilization facility members face—at best—the burdens of re-designing their facilities and installing new equipment to try to meet those standards and—at worst—the possibility that they will not be able to bear such costs and will have to cease operations. EOSA accordingly has challenged EPA's separate rule regulating ethylene oxide emissions from sterilization facilities[2] in another pending case, No. 24-1180. EOSA seeks to weigh in as an amicus supporting Petitioners here to further explain how EPA's expansive view of its authority under

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[1] No counsel for any party authored this brief in whole or part. No entity or person, aside from amicus curiae, its members, or its counsel, made any monetary contribution to fund the preparation or submission of this brief. All parties have consented to the filing of this brief.

[2] 89 Fed. Reg. 24,090 (Apr. 5, 2024) (the "Sterilizer Rule").

Section 112(f)(2) is unlawful, illogical, and harmful to U.S. businesses including sterilization facilities and their medical industry customers.

SUMMARY OF ARGUMENT

The Supreme Court has cautioned that courts should be wary of an agency's attempt to "discover in a long-extant statute an unheralded power." *Utility Air Regulatory Group v. EPA*, 573 U.S. 302, 324 (2014). That is exactly what EPA has done in this Rule, as well as in the Sterilizer Rule—EPA's other 2024 rulemaking similarly premised on a novel second round of residual risk review under CAA Section 112(f)(2).

Before these two rules, EPA had never attempted to regulate sources of HAP emissions a second time under Section 112(f)(2), instead rightly relying on its authority to revise emission standards based on its periodic consideration of technological improvements under Section 112(d)(6). That is the correct approach. It comports with the scheme Congress constructed in 1990, which includes a carefully timed sequence of regulatory events. And that longstanding approach also rightly requires EPA to consider the benefits of further tightening its Section 112 standards against the costs of doing so.

Now, EPA claims it can increase standards at any time, with no consideration of whether the benefits outweigh the costs, thus allowing the Agency to avoid a key part of the rational decision-making process. This Court should be very wary of allowing EPA to belatedly discovery and exercise such open-ended authority to regulate. This interpretation of Section 112(f)(2) will not only harm regulated industries, but also interrupt the supply of products essential to the lives and health of Americans. For example, EtO is the *only* means of sterilizing certain medical devices, and EPA's new, extremely stringent emission standards set forth in the Sterilizer Rule—requiring them to eliminate up to 99.99% of EtO emissions from sources within their facilities—is likely to cause a significant number of sterilizers to go out of business. That, in turn, could limit the availability of critical medical devices such as catheters, causing harm to human health that far exceeds the benefits EPA claims that either the HON Rule or the Sterilizer Rule will have.

In short, the consequences of EPA's exercise of its newfound authority to regulate repeatedly without any consideration of costs are profound, illogical, and even absurd. This Court should reject the Agency's novel and expansive view of its authority under Section

112(f)(2), and direct it to return to its prior approach, which allows EPA to periodically review and revise HAP emission standards in a way that makes sense and does not decimate critical industries and supply chains.

ARGUMENT

I. The statutory scheme and legislative history of CAA Section 112 do not allow for a second round of risk review.

Petitioners have ably explained why EPA's interpretation of Section 112 as allowing it to conduct a second round of risk review under Section 112(f) is wrong as a matter of statutory text. EOSA seeks to supplement that explanation by drawing the Court's attention to certain aspects of the statutory scheme that reinforce Petitioners' conclusion.

As a threshold matter, this Court should bear in mind that this is an issue of pure statutory construction. And as the Supreme Court clarified in *Loper Bright Enterprises v. Raimondo,* "courts, not agencies, will decide '*all* relevant questions of law' arising on review of agency action" and must "independently interpret the statute and effectuate the will of Congress." 603 U.S. 369, 392, 395 (2024) (quoting 5 U.S.C. § 706)). When addressing statutory interpretation issues, courts "begin with the text." *Eagle Pharms., Inc. v. Azar*, 952 F.3d 323, 330 (D.C. Cir. 2020) (internal quotation omitted). But they then look to the statute's structure

to "interpret the statute as a symmetrical and coherent regulatory scheme, and fit, if possible, all parts into an harmonious whole." *Id.* at 332 (internal quotation omitted). And while legislative history cannot overcome contrary statutory text, "exhaust[ing] the traditional tools of statutory construction" includes "examining the statute's legislative history to shed new light on congressional intent." *Id.* at 338 (quoting *Sierra Club v. EPA*, 551 F.3d 1019, 1027 (D.C. Cir. 2008) (internal quotation omitted)).

Here, the statutory context and legislative history solidify what the text conveys: that residual risk review under Section 112(f)(2) is a one-time event, while technology review under Section 112(d)(6) is a periodic, recurring obligation. There are at least three reasons this is so.

First, EPA's argument for allowing the agency to conduct a second round of risk review boils down to this: Congress did not explicitly say that it cannot. That is wrong for the reasons explained by Petitioners, including that agencies only have the authority that Congress affirmatively gives them. *See* Pet. Br. at 31, citing *Hikvision USA, Inc. v. FCC*, 97 F.4th 938, 944 (D.C. Cir. 2024). But even if, in some other statutory context, the absence of a regulatory bar might be construed as

a grant of authority, it cannot be so construed here given that in several other parts of Section 112—including subsection (d)—Congress explicitly gave EPA the authority to revise prior standards it now claims to have under Section 112(f). Congress's choice to make EPA's technology review under Section 112(d)(6) a recurring obligation but exclude such language from Section 112(f)(2), the residual risk review provision, can only be read as an intentional limitation of the latter to a single, contingent instance in time. *See Hamdan v. Rumsfeld*, 548 U.S. 557, 578 (2006) ("A familiar principle of statutory construction . . . is that a negative inference may be drawn from the exclusion of language from one statutory provision that is included in other provisions of the same statute.") (citation omitted). Here, the revisionary power EPA now claims is explicitly included not only in other parts of the same statute, but in another subsection of the very same CAA provision, Section 112. *Hamdan's* "familiar principle" mandating a negative inference thus applies with double force here.

Second, the residual risk review is contingent on a specific sequence of prior events that have only occurred once, decades ago. Even if these statutory prerequisites could be met a second time, that has not happened here.

The Section 112 regulatory sequence, as amended by Congress in 1990, begins with initial promulgation of standards by a certain deadline. *See* 42 U.S.C. § 7412(e)(1)(E) (requiring standards for all industrial categories to be "promulgated not later than 10 years after November 15, 1990"). Importantly, that mandate was made practicable by requiring that "maximum achievable control technology" or "MACT" standards be set according to "application of measures, processes, methods, systems or techniques" after "taking into consideration the cost of achieving such emission reduction." *Id.* § 7412(d)(2).

EPA was also required to submit to Congress a report on how to address any remaining human health risk at a particular point in time: "[n]ot later than 6 years after November 15, 1990." 42 U.S.C. § 7412(f)(1). The report must address the residual risk program broadly (including, for example, methods for calculating such risk) as well as fact-specific conclusions regarding specific remaining health risks (for example, "the actual health effects with respect to persons living in the vicinity of sources"). *Id.* If Congress fails to act on any recommendations in that report, then EPA "shall, within 8 years after promulgation of [initial]

standards," establish residual risk standards if needed "to provide an ample margin of safety to protect public health." *Id.* § 7412(f)(2)(A).

EPA submitted its required report to Congress in 1999. *See* EPA Office of Air Quality Planning and Standards, *Residual Risk Report to Congress*, EPA-453/R-99-001 (1999). It thereafter undertook its one-time residual risk review for both the sources regulated by this Rule as well as the EtO sterilizer facilities regulated by the Sterilizer Rule. And like the former, the latter were the subject of a 2006 rule that included EPA's conclusions regarding risk. *See* 71 Fed. Reg. 17,712 (Apr. 7, 2006).

Even assuming EPA could submit a second, updated report to Congress recommending further action to address risks from ethylene oxide emissions, it has never done so. Congress, in turn, has not failed to act on any such further report of residual risks—and therefore EPA has no authority to issue another round of residual risk standards. *See* 42 U.S.C.§ § 7412(f)(2)(A). EPA cannot simply bypass initial steps of a tiered statutory scheme to re-do a later step that is dependent on, and timed in relation to, those earlier steps.

Perhaps the most compelling aspect of EPA's contrary argument is the assertion that surely the Agency must be allowed to revise a risk-

based standard where it has found that there is more risk than EPA previously thought. To be sure, there is appeal to that argument—but only on the surface. EPA's argument wrongly assumes that residual risk review is the only tool in the Agency's toolbox to address risk from HAP, as opposed to one standard-setting step in a layered regulatory process intended to balance competing concerns including risk, costs (both economic and social), the state of emission control technology, and Congress's own prerogative (reserved via the statutory requirement for EPA to submit a report on residual risks and give Congress a chance to act) to take the first crack at assessing and addressing new claims of risk from HAP. In short, EPA's argument for expanding its authority under Section 112(f)(2) ignores the rest of the statutory scheme.

Finally, the legislative history of section 7412 also indicates that Congress did not intend for EPA to undertake residual risk review under Section 112(f)(2) more than once.

As originally enacted, Section 112 was impracticable because it did not authorize EPA to take cost into account when setting emissions standards, unlike other concurrently adopted provisions of the CAA. *See, e.g.*, 42 U.S.C. § 7411(a) (1970). For the next twenty years, section 7412

led to "a lot of action, but nothing final." H.R. Rep. No. 101-490, 101st Congress (1989), at 151.

The 1990 amendments transformed a previously stymied regulatory process by directing EPA, in Section 112(d), to promulgate standards not solely based on health risks, but rather on achievable control technology with considerations of cost and feasibility. Congress thereby "force[d] regulatory action to overcome the inertia that has plagued the *health-based*, standard-setting process authorized by current law." S. Rep. No. 101-228 (Dec. 10, 1989), at 156 (emphasis added). As this Court recently explained, the Section 112(d) "[technology] review ensures that, over time, EPA maintains source standards compliant with the law and on pace with emerging developments that create opportunities to do even better." *La. Env't Action Network v. EPA*, 955 F.3d 1088, 1093 (D.C. Cir. 2020).

The residual risk review provision was kept in the 1990 version of Section 112 as a fallback program incorporating preexisting language. *See* 136 Cong. Rec. S16,895, S16,932 (Oct. 27, 1990) ("We simply return to current law in the [residual risk] phase and ask EPA to set standards which provide an ample margin of safety to protect public health. That is

the current law standard. It is also the reason that very little has been done . . . over the past 20 years."). It was intended to function as a "safety net" to the initial technology review process. *See* 136 Cong. Rec. at S16,979. But Congress would not have gone through the trouble of adding the recurring technological review requirement if it intended that EPA also would keep performing periodic risk reviews whenever it saw fit.

If there is any deficiency in the statutory scheme—which EOSA does not believe is the case given Congress's enactment of multiple, layered review and regulation processes, including the initial round of MACT regulation under Section 112(d)(2); the one-time residual risk review under Section 112(f)(2), teed off by EPA's submission of a risk report to Congress and Congress's decision not to act on that report; and the eight-year recurring technology reviews required by Section 112(d)(6)—it is for Congress to amend it, not EPA.

II. EPA's new interpretation of Section 112(f)(2) allows it to perpetually bypass any consideration of costs.

There is another reason why EPA's expansive view of Section 112(f)(2) as allowing it to conduct endless rounds of risk review is wrong: it renders the obligation Congress imposed on EPA in Section 112(d) to consider the costs of increasing the stringency of HAP standards a

nullity. *See* 42 U.S.C. § 7412(d)(2) (requiring EPA to "tak[e] into consideration the cost of achieving such emission reductions" when conducting a technology review); *Nat'l Ass'n for Surface Finishing v. EPA*, 795 F.3d 1, 5 (D.C. Cir. 2015) ("In the technology review, EPA periodically assesses . . . the cost and feasibility of developments and corresponding emissions savings."). Even without an explicit instruction to consider cost, an agency must ordinarily do so because cost is "a centrally relevant factor when deciding whether to regulate," and "reasonable regulation ordinarily requires paying attention to the advantages *and* the disadvantages of agency decisions." *Michigan v. EPA*, 576 U.S. 743, 753 (2015).

As Petitioners explained, EPA's cost-agnostic approach to the Rule allowed the Agency to increase the stringency of hazardous pollutant standards without first determining if the associated costs are reasonable and outweigh the benefits. Pet. Br. at 35–37. The same is true for the Sterilizer Rule. There, EPA estimated the Rule's total annual costs will be around $88 million. 89 Fed. Reg. at 24,137. According to the Small Business Association ("SBA"), many U.S. sterilizers will need to spend over 20% of their revenue on compliance annually, which will force a

significant number of sterilizers to exit the market entirely.[3] Yet, because Section 112(f)(2) does not mandate consideration of cost (unlike Section 112(d)), EPA declined to assess whether the stringent standards imposed thereunder have reasonable associated costs and will result in benefits that outweigh those costs, including to medical providers and patients.

To regulate reasonably, EPA must—as a simple matter of logic as well as of law—consider whether the costs it is imposing on regulated sterilizers, plus the costs and harms it is imposing on users of sterilized medical devices (medical providers and patients), are outweighed by the benefits of regulation. As Justice Powell once explained "a standard-setting process that ignored economic considerations would result in a serious misallocation of resources and a lower effective level of safety." *Indus. Union Dept., AFL-CIO v. Am. Petroleum Inst.*, 448 U.S. 607, 659 (1980) (Powell, J., concurring). That is precisely what has happened both here and in the Sterilizer Rule.

[3] SBA Comments on Proposed Sterilizer Rule, EPA-HQ-OAR-2019-0178-0541, at 6, 12.

III. EPA's new interpretation of Section 112(f)(2) is disruptive and will create absurd results.

Finally, even if this Court set aside the normal agency obligation to consider the costs of increasing the stringency of a regulation, the results of EPA's new interpretation of Section 112(f)(2) in this Rule and the Sterilizer Rule are deeply problematic. These Rules will disrupt supply chains and carefully designed industrial processes, potentially causing safety and health harms that could quickly outweigh their claimed emission reduction benefits. Section 112 should be interpreted in a way that avoids such absurd results. *See Sinclair Wyoming Ref. Co. LLC v. EPA*, 101 F.4th 871, 884 (D.C. Cir. 2024) (rejecting reading of CAA provision addressing biofuel production that would cause an absurd result at odds with the statutory scheme).

As Petitioners explain, the Rule challenged here will result in serious harms if left in place, including increased safety risks to workers. *E.g.*, Pet. Br. at 69–70 (discussing Rule's interference with pressure releases that avoid catastrophic explosions that could harm workers and increase emissions). So too for the Sterilizer Rule. There, EPA imposed standards that will likely cause a significant number of medical sterilizers to cease operations, and the remainder to halt operations to

re-design their facilities, install new equipment, and test that equipment. That will interrupt the domestic supply of sterilized medical devices.[4] And some medical devices, such as catheters, are only sterilized by a few specialized facilities.[5] A shortage of such a device, used by medical providers to treat patients with both acute and chronic conditions, might have extremely dire consequences, including serious illness or death.

If even one patient death resulted from a medical device shortage, that would wipe away the claimed benefits of the Sterilizer Rule. And yet, in EPA's view, it need not even consider that possibility, much less weigh it against the Agency's claim that the Rule would have the benefit of a very small reduction in lifetime cancer risk. That is an absurd interpretation of Section 112, and it will have absurd results in the form of physical and social harms that EPA (in its view) has no obligation to even consider. This is exactly the type of situation where this Court has deployed the "absurd results" canon of construction to avoid such irrationality and harm. *See Sinclair Wyoming Ref.*, 101 F.4th at 884

[4] *See* SBA Comments on Proposed Sterilizer Rule, EPA-HQ-OAR-2019-0178-0541, at 6, 12.

[5] *See* Advanced Med. Tech. Ass'n Comments on Proposed Sterilizer Rule, EPA-HQ-OAR-2019-0178-0601, Attach. 1, at 11.

(interpreting CAA biofuels provision to avoid absurd result); *Media Matters for America v. Paxton*, 732 F. Supp. 3d 1, 16 (D.D.C. 2024) (rejecting interpretation of "person" as used in DC's long-arm statute that "would produce absurd results"). The Court should do so again here.

CONCLUSION

For these reasons and those in Petitioners' brief, this Court should hold unlawful EPA's assertion of authority to regulate repeatedly under CAA Section 112(f)(2) and set aside the challenged parts of the Rule.

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limitation contained in Fed. R. App. P. 29(a)(5) because, excluding the portions exempted by Rule 32(f), this brief contains 3,122 words.

This document complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type-style requirements of Fed. R. App. P. 32(a)(6) because this document has been prepared in a proportionally spaced typeface using Microsoft Word 2019 in 14-point Century Schoolbook.

/s/ Amanda Shafer Berman
Amanda Shafer Berman

CERTIFICATE OF SERVICE

I hereby certify that on January 24, 2025, I have caused the foregoing to be filed electronically with the Clerk of the United States Court of Appeals for the District of Columbia Circuit through the appellate CM/ECF system. I certify that all participants in the case are registered CM/ECF users and that service will be accomplished by the CM/ECF system.

/s/ Amanda Shafer Berman
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